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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/578,453 | 05/26/2000 | Jacques Mallet | 03804.0114-02 | 9203 |

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WASHINGTON, DC 20005-3315

EXAMINER

SHUKLA, RAM R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 05/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application N . | Applicant(s) | |
| | 09/578,453 | MALLET ET AL. | |
| | Examin r | Art Unit | |
| | Ram R. Shukla | 1632 | |

-- The MAILING DATE of this communication appears n the c ver sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____ .
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' response and amendments filed 2-19-03 have been received and entered.
2. Claims 27-31 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.
3. This application contains claims 27-31 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
4. Claims 16-26 are under consideration.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16, 17, 19, 20, 21, 22, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michalovitz et al (Cell 62: 671-680, 1990) in view of Moberg et al (Journal of Cellular Biochemistry 49:208-215, 1992) and La Gal La Salle (Science 259: 988-990, 1993) for reasons of record set forth in the previous office action of 4-11-02 and 11-19-02.

Response to Arguments

Applicant's arguments filed 11-19-02 have been fully considered but they are not persuasive.

Applicants have argued that the Examiner has mischaracterized the teachings of Michalovitz and Moberg and cite the abstract of the Michalovitz in support of their argument that Michalovitz teaches that mutant p53 teaches transformation. Applicants' arguments are not persuasive and are rather misleading because they have ignored the teachings of the Michalovitz that specifically teaches a temperature sensitive mutant p53val123 that suppresses transformation at 32.5 degree celcius. It is noted that Michalovitz et al a nucleic acid that encodes a mutated p53 which inhibits transformation. Likewise applicants arguments regarding Moberg is not persuasive because contrary to applicants arguments, Moberg teaches inhibition of c-myc promoter by wild type p53 and its teaching is that c-myc promoter is responsive to p53 regulation. In contrast to applicants' arguments that Examiner has not provided motivation, as noted in the previous office action, the motivation was to use p53 mutant for inhibiting expression of wild type p53. Likewise motivation to make adenoviral vectors comes from La Gal Salle, which teaches to use adenoviral vectors for transferring gene in brain both in vitro and in vivo. Applicants arguments that nothing in the prior art suggests the desirability of making an oncogenic adenovirus using mutant p53 is not persusasive because the claimed invention is not to any oncogenic adenovirus but to a recombinant virus or adenovirus that comprises a nucleic acid encoding a mutant form of p53 which antagonizes the effect of wild type p53. Applicants have not provided any evidence to support their arguments.

8. Claims 16-20, 22, 23, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levrero et al. taken with Michalovitz et al. and Funk et al., and further in view of Chopp et al for reasons of record set forth in the previous office action of 11-19-02.

Applicant's arguments filed 11-19-02 have been fully considered but they are not persuasive. As discussed above applicants argue that there is no evidence of record to suggest that p53 mutants or binding sites with effects on oncogenesis would have any activity in either enhancing or antagonizing any potential effect of wild type p53 on cell death. It is reiterated that the claims directed to the vectors

do not recite any such limitations. Regarding the argument about obvious to try, it is noted that applicants have not provided any evidence as to why an artisan of skill would not have been able to successfully make the vectors. Applicants' arguments that combination of the references would produce an oncogenic virus is irrelevant because the Micahlovitz teaches a mutant p53 that inhibits transformation.

Regarding applicants arguments that Chopp's observation is preliminary is not persuasive because there is not requirement that the motivation can not come from a preliminary observation. Again applicants arguments that there is not evidence of record to suggest that p53 mutants or binding sites with effects on oncogenesis would have any effect on wild type p53 on cell death is not persuasive because Micahlovitz taught that p53 mutant inhibited transformation and applicants have not provided any evidence why the mutant will not have effect on cell death in view of the results of Michalovitz, Chopp, Funk and Levaro. It is reiterated that Funk et al. (Molecular and Cellular Biology, 1992) disclosed a specific DNA binding site for p53 identical to that of Sequence ID No. 2 (page 2866, abstract).

9. Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith taken with Soussi et al., and further in view of Chopp et al for reasons of record set forth in the previous office action of 11-19-02.

Applicant's arguments filed 11-19-02 have been fully considered but they are not persuasive. Applicants argue that Smith does not teach blocking mRNA transcribed from p53 gene. It is noted that if Smith taught that the rejection would have been 102. While Soussi does not teach oligonucleotide, it teaches the p53 nucleic acid or which SEQ ID NO 1 is a part. Accordingly, in view of the teachings of Soussi et al. and Chopp et al., it would have been obvious for one of ordinary skill in the art at the time the claimed invention was made, to modify the method of Smith by administering a p53 antisense oligonucleotide for the expected effect of suppressing p53 activity by inhibition. Thus, Applicant's claimed invention as a whole, was clearly *prima facie* obvious in the absence of evidence to the contrary.

10. No claim is allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



RAM SHUKLA
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632